Safety and Tolerability Study of Neural Stem Cells (NR1) in Subjects with Chronic Ischemic Subcortical Stroke

Grant Award Details

Safety and Tolerability Study of Neural Stem Cells (NR1) in Subjects with Chronic Ischemic Subcortical Stroke

Grant Type: Clinical Trial Stage Projects

Grant Number: CLIN2-12379

Project Objective: To conduct a first in human clinical trial of NR-1, hESC derived neural progenitor cells, in patients with chronic stroke. To identify the maximum tolerated NR1 dose in man, manufacture NR1 to support the study, and to further develop potential potency assays for NR1.

Investigator:

Name:	Gary Steinberg
Institution:	Stanford University
Type:	PI

Disease Focus: Neurological Disorders, Stroke

Human Stem Cell Use: Embryonic Stem Cell

Award Value: $11,998,988

Status: Active

Grant Application Details

Application Title: Safety and Tolerability Study of Neural Stem Cells (NR1) in Subjects with Chronic Ischemic Subcortical Stroke

Public Abstract:

Therapeutic Candidate or Device

A human embryonic derived, non-genetically modified neural stem cell (NR1), originally derived from the Wi-Cell H-9 line

Indication

Patients with chronic motor deficits, from 6 to 60 months after stroke. NR1 cells will be injected into the brain near the site of the stroke.

Therapeutic Mechanism

The proposed therapeutic mechanism of action of NR1 neural stem cells is the secretion of factors that enhance the brain's own ability to heal itself after stroke, including the creation of new blood vessels to replace those that were injured beyond repair, and modulation of the immune system.

Unmet Medical Need

Strokes are a leading cause of adult disability. There is no medical therapy able to promote recovery in chronic stroke patients, establishing stroke as a major unmet medical need. NR1 cells will be the first stem cell-derived therapy directed towards improving disability for this disease.

Project Objective

Complete a Phase 1 / Phase 2a trial with analysis

Major Proposed Activities

- Complete a Phase 1 / Phase 2a Clinical Trial for NR1 treatment after stroke and initial data analysis
- Manufacture a cGMP NR1 working cell bank and clinical lot
- Complete the potency assay and stability program development

Statement of Benefit to California:

This program provides several areas of benefit to California as the first stem cell-derived therapy for recovery of function after stroke. It will provide medical benefits by treating disabled Californians. It will provide an economic benefit as a medical therapy that is manufactured and tested within the state. It will provide scientific benefit by pioneering the science of brain repair in California universities, with likely spin-off of additional novel therapies for neurological disease.

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